

PTO/SB/21 (09-04)

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Application Number

10702,194

Filing Date

November 4, 2003

First Named Inventor

Stephen Solomon et al.

Art Unit

3761

Examiner Name

Melanie Hand

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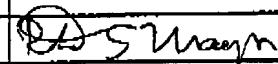
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Attorney Docket Number 11973-003

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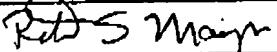
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Message

In re the Application of:

Stephen Solomon et al.

Application No.: 10/702,194

Filed: November 4, 2003

For: FOOD EXTRACTION APPARATUS
AND METHOD

Group Art Unit: 3761

Examiner: Melanie Hand

REPLY TO EXAMINER'S ANSWER

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Attorney Docket: 11973-003

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In re the Application of:

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Application No.: 10/702,194

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For: FOOD EXTRACTION APPARATUS
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Group Art Unit: 3761

Examiner: Melanie Hand

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REPLY TO EXAMINER'S ANSWER

Sir:

This paper is a response to the Examiner's Answer mailed May 7, 2007, a response to
which is due on Monday, July 9, 2007.

The Commissioner is authorized to charge any fees required in connection with this paper
to Deposit Account No. 16-2500.

Application No. 10/702,194
Attorney Docket: 11973-003

Status of Claims

Claims 17, 18 and 32-34 are pending and are the subject of this appeal. Claims 17 and 32-34 are independent. Claims 32-34 stand rejected under 35 U.S.C. § 112, second paragraph. Claims 17, 18 and 32-34 stand rejected under 35 U.S.C. § 103 as being unpatentable over Shapiro. Claims 1-15 and 20 were previously withdrawn as not directed to the elected invention. Claims 16, 19 and 21-31 were previously cancelled without prejudice or disclaimer.

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Grounds of Rejection to Be Reviewed on Appeal

I. Whether claims 32-34 fail to set forth the subject matter which applicants regard as their invention under 35 U.S.C. § 112, second paragraph.

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II. Whether claims 17 and 18 are unpatentable under 35 U.S.C. § 103 over Shapiro.

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III. Whether claims 32-34 are unpatentable under 35 U.S.C. § 103 over Shapiro.

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Argument

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a. Introduction

Obesity is a medical condition with a well-accepted definition: an adult is considered to be obese when their body mass index (BMI) exceeds 30. See, e.g., the definition from the Centers for Disease Control and Prevention Agency of the United States Department of Health and Human Services ("the CDC"), attached as Appendix A; and the overweight and Obesity classification table from the National Institute of Health, attached as Appendix B.¹

The Examiner's Answer fails to appreciate that obesity is a term with an accepted meaning, and apparently considers a person who has experienced any weight gain, no matter how small, as being "obese." This is clear from the last paragraph on page 7 of the Examiner's Answer, which states that "while the [subject] may not be obese upon the first cycle of ingesting foodstuffs, the rat necessarily becomes obese prior to the drawing out of said foodstuffs." It is also clear from the next sentence, which states that "[b]ulimics can also be considered obese," even though bulimia and obesity are two distinct medical conditions, and most bulimics are not obese. See the CDC glossary entry for bulimia, attached as Appendix C, which defines bulimia as "a disorder marked by morbidly increased appetite, often alternating with periods of anorexia." Notably, the definition of bulimia is not dependent on BMI or obesity.

Although ingesting one pound of food at a single meal will temporarily cause a person's weight to increase by one pound, ingesting that single meal does not make the person obese because it does not cause the person's BMI to increase above the threshold of 30. Since being

¹ It was necessary to add Appendices A-C in this Reply to address the Examiner's incorrect interpretation of "obese," which appeared for the first time in the Examiner's Answer.

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“obese” has an accepted medical definition, the claims’ references to “obese” must be read in view of that definition.

b. The Rejections of Claims 32-34 under 35 U.S.C. § 103 and § 112, ¶ 2

Claims 32 and 33 recite the steps of introducing a tube or passageway through an obese patient’s abdominal wall, allowing the obese patient to ingest food, extracting the food from the obese patient, and repeating the steps of ingesting and extracting food until the patient is no longer obese. Claim 34 is similar to claims 32 and 33 except that claim 34 does not recite the step of introducing a tube or passageway through the obese patient’s abdominal wall. Since Shapiro does not describe the steps of introducing a tube or passageway through an obese patient’s abdominal wall, allowing the obese patient to ingest food, or extracting the food from the obese patient, applicants submit that the limitations recited in the claims are not taught or suggested by Shapiro, which was a study designed to mimic bulimia.

The significance of the limitations reciting that the patient must be obese in claims 32 - 34 is supported by *Perricone v. Medicis Pharmaceutical Corp.*, 77 USPQ2d 1321 (Fed. Cir. 2005). In situations when a new use is positively recited in the steps of a method claim, “new uses of old products or processes are indeed patentable subject matter.” *Id.* Following the same reasoning, in order to properly reject claims 32-34, the Examiner has the burden of finding prior art where food was extracted from the upper digestive system of an obese patient, and where it is done via a tube or passageway through the obese patient’s abdominal wall. Since Shapiro fails to teach or suggest “extracting the food from the upper digestive system of [an] obese patient,” this limitation is not satisfied by the cited art.

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In addition, the limitation of “repeating steps...until the patient is no longer obese.” constitutes a time-related limitation that specifies how long the previous steps must be repeated, i.e., until such time that the subject is no longer obese. This is another concept that is neither taught nor suggested by Shapiro, which was an experiment designed to mimic bulimia – not obesity. Since bulimia and obesity are two independent diseases, as explained above, the Examiner’s reliance on Shapiro is not appropriate in the context of obesity.

Finally, Applicants’ reiterate their understanding of Shapiro as an author who is critiquing the use of animal models in eating disorder research. (See page 111). Applicants do not take Shapiro out of context since Shapiro states “[i]n the second part, I provide a critique of the particular models presented.” Shapiro at page 111. Shapiro does mock the use of animal research in understanding eating disorders. This is apparent from his sarcastic remark found at page 144 in which he rhetorically asks, “[w]hat could be more farfetched than studying the peculiar and apparently culturally driven psychology and behavior of bulimia by observing the eating behavior of a rat whose stomach has a hole cut into it...?” Ultimately, the author reaches the conclusion that “animal models have contributed virtually nothing toward the effective treatment of eating disorders.” (See page 210). Accordingly, Applicants submit that it would not have been obvious to modify the method in Shapiro for the purpose of treating obese patients. Shapiro teaches away from the use of animal models in treating eating disorders. A reference that teaches away cannot render claims obvious.

Since claims 32-34 contain limitations that are neither taught nor suggested by Shapiro, Applicants submit that those claims are not obvious over that reference, and respectfully request reversal of the rejection of those claims under 35 U.S.C. § 103. In addition, since neither the

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steps of the methods recited in claims 32-34 nor the results obtained when those methods are performed are the same as in Shapiro (the results differ because bulimics usually do not loose weight despite their binge-purge behavior). Applicants respectfully request reversal of the rejections under 35 U.S.C. § 112, second paragraph.

c. The Rejections of Claims 17 and 18 under 35 U.S.C. § 103

The last two steps of claim 17 are: [a] monitoring a volume of the pumped food; and [b] ending the pumping when the monitored volume exceeds preset parameters within a given time. Even if one were to accept the Examiner's argument that the "monitoring" step is inevitably performed by the pump operator, the Examiner has not pointed to anything in Shapiro that teaches or suggests "ending the pumping when the monitored volume exceeds preset parameters within a given time," and has proposed no motivation why a person of ordinary skill might be led to end the pumping at such time.

To the contrary – since the last paragraph of page 125 of Shapiro describes sham feeding as a process in which "the animal eats or drinks without receiving nutritional benefits," a person following the teachings of Shapiro would not be motivated to end the pumping after a certain volume has been pumped out within a given time. Instead, a person following the teachings of Shapiro would be motivated to continue pumping until as much food as possible has been removed. Applicants therefore submit that the Examiner has not made a prima facie case of obviousness because "to establish a prima facie obviousness of a claimed invention, all the claim limitation must be taught or suggested by the prior art." *See* M.P.E.P. § 2143.03. Applicants therefore respectfully ask the Board to reverse this rejection as well.

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Attorney Docket: 11973-003

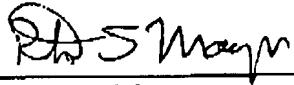
Applicants' undersigned attorney may be reached by telephone at (212) 969-3686 or by facsimile at (212) 969-2900. Please continue to direct all correspondence to Customer No. 21890 at the address provided below.

Respectfully submitted,

PROSKAUER ROSE LLP

Date: July 6, 2007

By:



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APPENDIX A



Defining Overweight and Obesity

Overweight and obesity are both labels for ranges of weight that are greater than what is generally considered healthy for a given height. The terms also identify ranges of weight that have been shown to increase the likelihood of certain diseases and other health problems.

Definitions for Adults

For adults, overweight and obesity ranges are determined by using weight and height to calculate a number called the "body mass index" (BMI). BMI is used because, for most people, it correlates with their amount of body fat.

- An adult who has a BMI between 25 and 29.9 is considered overweight.
- An adult who has a BMI of 30 or higher is considered obese.

See the following table for an example.

Height	Weight Range	BMI	Considered
5' 9"	124 lbs or less	Below 18.5	Underweight
	125 lbs to 168 lbs	18.5 to 24.9	Healthy weight
	169 lbs to 202 lbs	25.0 to 29.9	Overweight
	203 lbs or more	30 or higher	Obese

It is important to remember that although BMI correlates with the amount of body fat, BMI does not directly measure body fat. As a result, some people, such as athletes, may have a BMI that identifies them as overweight even though they do not have excess body fat. For more information about BMI, visit [Body Mass Index](#).

Other methods of estimating body fat and body fat distribution include measurements of skinfold thickness and waist circumference, calculation of waist-to-hip circumference ratios, and techniques such as ultrasound, computed tomography, and magnetic resonance imaging (MRI).

Definitions for Children and Teens

For children and teens, BMI ranges above a normal weight have different labels (at risk of overweight and overweight). Additionally, BMI ranges for children and teens are defined so that they take into account normal differences in body fat between boys and girls and differences in body fat at various ages. For more information about BMI for children and teens (also called BMI-for-age), visit [BMI for Children and Teens](#).

<http://www.cdc.gov/print.do?url=http%3A%2F%2Fwww.cdc.gov%2Fnccdphp%2Fdnpa%2Fobesit...> 7/6/2007

Assessing Health Risks Associated with Overweight and Obesity

BMI is just one indicator of potential health risks associated with being overweight or obese. For assessing someone's likelihood of developing overweight- or obesity-related diseases, the National Heart, Lung, and Blood Institute guidelines recommend looking at two other predictors:

- The individual's waist circumference (because abdominal fat is a predictor of risk for obesity-related diseases).
- Other risk factors the individual has for diseases and conditions associated with obesity (for example, high blood pressure or physical inactivity).

For more information about the assessment of health risk for developing overweight- and obesity-related diseases, visit the following Web pages from the National Heart, Lung, and Blood Institute:

- [Assessing Your Risk](#)
- [Body Mass Index Table](#)
- [Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults](#)

[back to top](#)

 Please note: Some of these publications are available for download only as *.pdf files. These files require Adobe Acrobat Reader in order to be viewed. Please review the [information on downloading and using Acrobat Reader software](#).

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Page last reviewed: May 22, 2007

Page last updated: May 22, 2007

Content Source: [Division of Nutrition and Physical Activity, National Center for Chronic Disease Prevention and Health Promotion](#)

Page Located on the Web at <http://www.cdc.gov/nccdphp/dnpa/obesity/defining.htm>

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
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APPENDIX B

NHLBI, Classification and Risks of Overweight and Obesity

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DEPARTMENT OF HEALTH AND HUMAN SERVICES • NATIONAL INSTITUTES OF HEALTH



National Heart Lung and Blood Institute • Obesity Education Initiative

Healthy Weight Home • BMI Calculator • Menu Planner • Portion Distortion • WebCast

Classification of Overweight and Obesity by BMI, Waist Circumference, and Associated Disease Risks

Disease Risk* Relative to Normal Weight and Waist Circumference

	BMI (kg/m ²)	Obesity Class	Men 102 cm (40 in) or less Women 88 cm (35 in) or less	Men > 102 cm (40 in) Women > 88 cm (35 in)
Underweight	< 18.5		-	-
Normal	18.5 - 24.9		-	-
Overweight	25.0 - 29.9		Increased	High
Obesity	30.0 - 34.9	I	High	Very High
	35.0 - 39.9	II	Very High	Very High
Extreme Obesity	40.0 +	III	Extremely High	Extremely High

* Disease risk for type 2 diabetes, hypertension, and CVD.

+ Increased waist circumference can also be a marker for increased risk even in persons of normal weight.

Back

Key Recommendations • Assessing Risk • Controlling Weight • Fall Prevention
 Shopping • What to Look For • Recipes • Sample Menus • Food Exchange List
 Selecting a Program • Guide to Physical Activity • Guide to Behavior Change • The Shape
 Dolls • Food and Activity Diary • e-Toolbox



Professional Education Materials • Parent & Public Education Materials
 Healthy Weight Home • BMI Calculator • Menu Planner • Portion Distortion • WebCast

NHLBI Home • OEP Home • NHLBI Privacy Statement • Contact the NHLBI • Accessibility

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APPENDIX C

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CDC - CFS Glossary

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B**bile duct**

Tubular structures responsible for conducting bile (a substance that aids in digestion) from the liver to the intestine.

biliary obstruction

Blockage or clogging of a bile duct.

bilirubin

A red pigment formed from hemoglobin during normal and abnormal destruction of red blood cells in the body.

bipolar affective disorder

A mood disorder that commonly begins with depression and is characterized by at least one period of elation sometime during the course of the illness.

Borrelia

A genus of bacteria with numerous species that cause disease in humans. The diseases associated with these organisms are typically relapsing fevers.

bulimia nervosa

A disorder marked by morbidly increased appetite, often alternating with periods of anorexia.